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EXAMINER	
BERTOGLIO, VALARIE E	
ART UNIT	**PAPER NUMBER**
1632	2

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/036,581	Applicant(s) ALIKANI ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 08 November 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

Specification

The abstract of the disclosure is objected to because the abstract is greater than 150 words in length and contains multiple paragraphs. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The composite blastocysts of claims 1-6, although comprised of cells from non-viable pre-embryos, are themselves viable, and appear to embrace human

embryos. The stem cells of claims 7 and 8 can also be read to encompass human embryos. The claims, therefore, encompass viable, human embryos. A human being is non-statutory subject matter. See 1077 O.G. 24, April 21, 1987.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims are 1-13 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Claims 1-13 encompass a composite blastocyst from all species of animals including non-mammalian species. The specification describes composite blastocysts from mammalian species, specifically primate and humans (page 8, paragraph 4; page 10, paragraph 3). The specification discloses that composite blastocysts are formed by aggregating cells from non-viable pre-embryos in a protective environment of a zona pellucida. Only mammalian species comprise embryos within a zona pellucida and therefore the specification only describes

aggregating mammalian cells from non-viable pre-embryos. The specification does not describe composite blastocysts from any non-mammalian species. Therefore, there is no evidence of record of a relationship between the structures of mammalian and non-mammalian composite blastocysts. There is no evidence of record that composite blastocysts of mammalian species would provide any reliable information about the structure of composite blastocysts of non-mammalian species. The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

In the instant case the embodiments of composite blastocysts from species other than mammals encompassed by the genus lack a written description. The specification fails to describe the other species of composite blastocysts that fall into this genus and it was unknown as of Applicants' effective filing date the other species of composite blastocysts existed.

With the exception of mammalian species, the skilled artisan cannot envision the detailed structure of the other composite blastocysts encompassed within the genus, and therefore conception is not achieved regardless of the complexity or simplicity of the method of preparation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by non-mammalian composite blastocysts encompassed by the claims. Therefore, only composite blastocysts comprising cells derived from mammalian, non-viable pre-embryos, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that "to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention".

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,4-6 and 9 are unclear because they use the term pre-embryo. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its

ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "pre-embryo" in claims 1,4-6 and 9 is used by the claim to mean "pre-blastocyst embryo", while the accepted meanings include "A fertilized ovum up to 14 days old, before it becomes implanted in the uterus" (The American Heritage® Dictionary of the English Language; http://www.bartleby.com/61/75/P0517550.html) or "A fertilized egg in the early stage of development prior to cell division. " (Biotech Lifescience Dictionary, http://biotech.icmb.utexas.edu/search/dict-search.phtml?title=pre-embryo). The term is indefinite because the specification does not clearly redefine the term. The term is made further unclear by the conflicting definitions of pre-embryo as some definitions require only pre-implantaion while others limit it to a zygote, i.e. prior to cell division. Claims 2 and 3 depend from claim1. Claim 7 depends from claim 1. Claim 8 depends from claim 6. Claims 10-13 depend from claim 9.

Claim 9 is incomplete as written. The preamble of the claim is directed to a method of producing composite blastocysts. However, the claim is incomplete because the steps of the methopd do not relate back to the preamble in a positive process. Appropriate correction is required. Claims 10-13 depend from claim 9 and are thus encompassed by this rejection.

Claim 11 is unclear because it recites the method of producing composite blastocysts of claim 9 wherein the cells used are derived from a viable embryo. However, the parent claim 9 does not encompass using cells from a viable embryo as it recites a limitation of non-viable pre-embryo (line 2). Therefore, claim 11 does not fall within the scope of parent claim 9. Appropriate correction is required.

Claims 12 and 13 are incomplete as written. They are drawn to a method of isolating stem cell lines but do not include method steps. Claims 12 and 13 include only the method of claim 9, which is drawn to producing composite blastocysts. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Luo (Nature, 1997, Vol. 388, pages 778-782).

Claims are directed to a preparation of composite blastocysts comprised of cells isolated from multiple, non-viable embryos. Claims recite that the CBs maintain the potential to differentiate (claim 2) into ectodermal, mesodermal and endodermal tissues (claim 3).

The term pre-embryo is not defined by the specification but is known in the art to include pre-implantation embryos (see above).

Luo teaches aggregating tetraploid mouse embryos, which are non-viable pre-embryos because they have not implanted in the uterus and cannot themselves develop into an embryo, with pre-implantation homozygous mutant embryos that are normally non-viable (page 778, column 2, lines 29-31), to generate rescued tetraploid aggregation chimeras which were then allowed to develop in foster female hosts to stage e12.5, which is beyond the blastocyst stage, at which time they were killed (page 782, column 1, last paragraph). The use of tetraploid cells rescued the ERR-beta mutant phenotype and the mutant chimeras appeared the same as wild-type (page 781, column 1, lines 20-21), This, composite embryos at E12.5 comprise tissue

derivatives of all three germ layers. Hence, Luo generated composite blastocysts comprising cells derived from non-viable tetraploid and ERR-beta mutant embryos that had the potential to differentiate into derivatives of ectodermal, mesodermal and endodermal origin. Therefore, the teachings of Luo anticipate all the limitations of claims 1-3.

2) Claims 1-3 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagy (PNAS, 1993, Vol. 90, pages 8424-8428).

Claims are directed to a preparation of composite blastocysts comprised of cells isolated from multiple, non-viable pre-embryos. Claims recite that the CBs maintain the potential to differentiate (claim 2) into ectodermal, mesodermal and endodermal tissues (claim 3). Claim 7 is directed a stem cell line.

The term pre-embryo is not defined by the specification but is known in the art to include pre-implantation embryos (see above).

Nagy taught aggregating tetraploid mouse embryos, which are non-viable pre-embryos because they have not implanted in the uterus and cannot themselves develop into an embryo, with ES cells, which are non-viable pre-embryos because they have the potential to develop into an embryo but cannot, in and of themselves, develop into a viable blastocyst (page 8424, column 2, last paragraph). The aggregation chimeras were then allowed to develop into live animals, which is beyond the blastocyst stage (page 8426, column 2, first full paragraph). Live animals possess tissue derivatives from all three germ layers and thus it is inherent that the cells at the blastocyst stage possessed the potential to differentiate into endoderm, mesoderm and ectoderm. Hence, Nagy generated composite blastocysts comprising cells derived from non-viable tetraploid embryos and ES cells. In addition, claim 7 is a product by process claim in which the process of creating the animal carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is

because the final product (a stem cell line) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed stem cell line are met by any stem cell line in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

Nagy taught mouse embryonic stem cells (page 8424, column 2, last paragraph), which are encompassed by the claimed stem cells of claim 7.

Thus, the teachings of Nagy anticipate the limitations of claims 1-3 and 7.

3) Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomson (Science, 1998. Vol. 282, pages 1145-1147).

Claims are directed to a stem cell line produced by the process of claim 1 (claim 7) or claim 6 (claim 8). Claim 7 encompasses any stem cell line and claim 8 is limited to human stem cell lines.

Claims 7 and 8 are a product by process claims in which the process of creating the animal carries little patentable weight, as explained above.

Thomson taught generating human embryonic stem cell lines from human blastocysts (page 1145, column 2, lines 8-12 and page 1147, reference 6).

Therefore, Thomson meets all of the limitations of claims 7 and 8.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Examiner
Art Unit 1632

PETER PARAS
PATENT EXAMINER